

### **REMARKS/ARGUMENTS**

Applicant has amended Claims 1, 4, 7, 8, 17, 21, 41, 43, 45, 52, and 53. Applicant has cancelled Claims 2-3, 18, 22, 24-40, and 54-60, and thus, the objections to and the rejections of Claims 2-3, 18, 22, 24-40, and 54-60 are moot. Claims 1, 4-17, 19-21, 23, and 41-53 are pending. Applicant respectfully requests reconsideration of the pending claims in view of the following remarks.

#### **CLAIM REJECTIONS – 35 U.S.C. § 102**

##### **Independent Claim 1**

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,117,828 issued to Metzger et al. (hereinafter “Metzger”).

Claim 1 specifies “said distal region having at least one expandable electrode and an electrode expanding means, the expandable electrode being longitudinally arranged.”

Metzger discloses a catheter 10 including a cylindrical body 12 with a proximal end 14 and a distal end 16. A flexible membrane 18 is carried on the distal end 16. The flexible membrane 18 can be expanded using an internal mechanical expansion apparatus 20. The flexible membrane 18 can include first and second cylindrical conductive members 22 and 24 coupled to the outer surface of the flexible membrane 18. *Metzger*, col. 3, lines 33-57. As shown in Figures 2 and 3 of Metzger, the first and second cylindrical conductive members 22 and 24 are positioned around a circumference of the flexible membrane 18 orthogonal to the cylindrical body 12. *Metzger*, Figures 2 and 3. Figures 4 and 6-8 of Metzger illustrate alternative embodiments of catheters 50 and 50a, each of which includes conductive members 64 and 66 or 70a, 70b, and 70c positioned around a circumference of insulative members 52a-52f. *Metzger*, col. 4, lines 50-59; Figures 4 and 6-8.

Accordingly, Metzger does not disclose “said distal region having at least one expandable electrode and an electrode expanding means, the expandable electrode being longitudinally

arranged,” as specified by Claim 1. Therefore, independent Claim 1 and dependent Claims 4-16 are allowable.

Dependent Claims 4-16

Claims 4-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Metzger. Claims 4-16 depend from Claim 1, and are therefore allowable for the reasons set forth above with respect to Claim 1. Claims 5-10 and 14-15 specify additional patentable subject matter not specifically discussed herein.

Claim 4 also specifies “wherein at least a portion of the expandable electrode is spirally arranged.” Metzger does not disclose an expandable electrode that is spirally arranged. Thus, Claim 4 specifies additional patentable subject matter.

Claim 11 further specifies “wherein the catheter has a lumen, and the electrode expanding means comprises a rod disposed within said lumen, and wherein the rod has a distal end connected to the expandable electrode so that the catheter forms a sheath over the expandable electrode means and the rod.” As noted above, Metzger discloses that the first and second cylindrical conductive members 22 and 24 are positioned around a circumference of the flexible membrane 18. Figure 2 of Metzger illustrates that the conductive members 22 and 24 are outside of a flexible plastic body 12. Metzger, col. 3, lines 39-40 and lines 56-57; Figure 2. In other words, the flexible plastic body 12 and the flexible membrane 18 are under the conductive members 22 and 24. Thus, Claim 11 specifies additional patentable subject matter.

In addition, Claim 12 specifies “wherein the electrode expanding means comprises an inflatable balloon.” Also, Claim 16 specifies “wherein the balloon has at least one ridge thereon to allow the passage of fluid therearound, and wherein at least one expandable electrode is attached to said ridge.” Metzger does not disclose any type of inflatable balloon. Thus, Claims 12 and 16 specify additional patentable subject matter.

Further, Claim 13 specifies “wherein the electrode expanding means comprises a metallic shape memory means.” Metzger does not disclose any type of metallic shape memory means. Thus, Claim 13 specifies additional patentable subject matter.

#### Independent Claim 17

Claim 17 stands rejected under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,381,499 issued to Taylor et al. (hereinafter “Taylor”).

Claim 17 specifies “a pair of electrically non-conducting members secured together in a pivotal relation so as to form confronting jaws” and “the electrode being shaped to avoid causing crush trauma to the nerve, the electrode including a concave portion that receives the nerve and at least one flat portion.”

Taylor discloses the use of minimally-invasive clips that provide electrical contact with the vagus nerve. *Taylor*, col. 5, lines 49-51. The clips of Taylor “bite gently into the nerve to provide positive electrical contact therewith as well as to prevent the clip from falling off the nerve.” *Taylor*, col. 7, lines 14-16. Figure 1 of Taylor illustrates electrodes that are entirely concave with no flat portions. Figures 5-5B of Taylor illustrate electrodes that are either flat or convex and triangular. Figures 6-6B of Taylor illustrate electrodes that are convex. Figures 7-17 of Taylor all appear to illustrate entirely flat electrodes. Figure 18 of Taylor illustrates electrodes with oppositely-facing notches 200. However, Figure 18 of Taylor does not illustrate a clip with pivotal, confronting jaws, as also specified by Claim 17. *Taylor*, col. 10, lines 33-45; Figure 18. Figures 19-21 of Taylor illustrate devices that pierce the nerve.

Accordingly, Taylor does not disclose “a pair of electrically non-conducting members secured together in a pivotal relation so as to form confronting jaws” and “the electrode being shaped to avoid causing crush trauma to the nerve, the electrode including a concave portion that receives the nerve and at least one flat portion,” as specified by Claim 17. Thus, independent Claim 17 and dependent Claims 19-20 are allowable.

### Dependent Claims 19-20

Claims 19-20 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor. Claims 19-20 depend from Claim 17, and are therefore allowable for the reasons set forth above with respect to Claim 17.

Claim 19 also specifies “wherein the electrode is compressible so that the electrode contacts a nerve to avoid causing crush trauma.” Taylor does not disclose a compressible electrode. Thus, Claim 19 specifies additional patentable subject matter.

Claim 20 further specifies “wherein the electrode is wire mesh or wire wool.” Taylor does not disclose an electrode constructed of wire mesh or wire wool. Thus, Claim 20 specifies additional patentable subject matter.

### Independent Claim 21

Claim 21 stands rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,282,468 issued to Klepinski (hereinafter “Klepinski”).

Claim 21 specifies “the electrode being positioned in a longitudinal traversing channel of an electrically non-conductive member.”

Klepinski discloses an electrode system 10 with a central spine 12 and fingers 14a-14n and 16a-16n that extend orthogonal to the central spine 12 and curve away from the central spine 12. *Klepinski*, col. 2, lines 55-65; Figure 1. Electrodes 18 are positioned on the inner surfaces of the fingers and follow the orthogonal curve of the fingers. *Klepinski*, col. 3, lines 7-10.

Accordingly, Klepinski does not disclose “the electrode being positioned in a longitudinal traversing channel of an electrically non-conductive member,” as specified by Claim 21. Thus, independent Claim 21 and dependent Claims 22-23 are allowable.

### Dependent Claims 22-23

Claim 22 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Klepinski. Applicant is assuming that Claim 23 were intended to be included in the rejection on page 2 of the Office action. Claims 22-23 depend from Claim 21, and are therefore allowable for the reasons set forth above with respect to Claim 21. Claim 22 specifies additional patentable subject matter not specifically discussed herein.

Claim 23 also specifies “wherein the electrode is wire mesh or wire wool.” Taylor does not disclose an electrode constructed of wire mesh or wire wool. Thus, Claim 23 specifies additional patentable subject matter.

### Independent Claim 41

Claim 41 stands rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,690,691 issued to Chen et al. (hereinafter “Chen”).

Claim 41 specifies “a nasogastric tube having an inflatable means of expanding an electrode and an electrode attached to said inflatable means so that when the inflatable means is inflated, the electrode contracts the inner surface of the esophagus.”

In the background section, Chen describes another patent (U.S. Patent No. 3,411,507) that discloses an electrode positioned on a nasogastric catheter that is inserted into the patient’s stomach and positioned in close proximity to the pylorus of the stomach. *Chen*, col. 2, lines 27-32. Regarding the Chen device itself, the electrodes 42, 44, and 46 are implantable on the inner or outer surface of the gastro-intestinal tract organ. *Chen*, col. 5, lines 18-24. However, Chen does not disclose any type of expandable and inflatable electrode.

Accordingly, Chen does not disclose “a nasogastric tube having an inflatable means of expanding an electrode and an electrode attached to said inflatable means so that when the inflatable means is inflated, the electrode contracts the inner surface of the esophagus,” as specified by Claim 41. Thus, independent Claim 41 and dependent Claims 42-44 are allowable.

#### Dependent Claims 42-44

Claims 42-44 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Chen. Claims 42-44 depend from Claim 41, and are therefore allowable for the reasons set forth above with respect to Claim 41. Claims 42-44 specify additional patentable subject matter not specifically discussed herein.

#### Independent Claim 45

Claim 45 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Chen.

Claim 45 specifies “a nasogastric tube having at least one expandable electrode thereon, so that the electrode contacts a wall of the esophagus when the electrode is expanded.”

In the background section, Chen describes another patent (U.S. Patent No. 3,411,507) that discloses an electrode positioned on a nasogastric catheter that is inserted into the patient's stomach and positioned in close proximity to the pylorus of the stomach. *Chen*, col. 2, lines 27-32. Regarding the Chen device itself, the electrodes 42, 44, and 46 are implantable on the inner or outer surface of the gastro-intestinal tract organ. *Chen*, col. 5, lines 18-24. However, Chen does not disclose any type of expandable electrode.

Accordingly, Chen does not disclose “a nasogastric tube having at least one expandable electrode thereon, so that the electrode contacts a wall of the esophagus when the electrode is expanded,” as specified by Claim 45. Thus, independent Claim 45 and dependent Claims 46-53 are allowable.

#### Dependent Claims 46-53

Claims 46-53 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Chen. Claims 46-53 depend from Claim 45, and are therefore allowable for the reasons set forth above with respect to Claim 45. Claims 46-53 specify additional patentable subject matter not specifically discussed herein.

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CONCLUSION

In light of the above, Applicant respectfully requests reconsideration and allowance of Claims 1, 4-17, 19-21, 23, and 41-53.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gerald L. Fellows", followed by a long horizontal line extending to the right.

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